

REMARKS

The Final Office Action of October 3, 2008, has been received and reviewed. The present response is filed under 35 U.S.C. § 1.114 in conjunction with a Request for Continued Examination. Claims 1, 6, 7, 9, and 21-29 are currently pending in the application. The claims are to be amended as previously set forth. New claims 28 and 29 are presented herein. Basis for new claims 38-20 can be found throughout the Specification and more specifically at ¶¶ 15, 57, 64, 75, 104-106 of the Specification as published. All amendments and claim cancellations are made without prejudice or disclaimer. No new matter has been presented. Reconsideration is respectfully requested.

Rejections under 35 U.S.C. § 112, First Paragraph, Written Description

Claims 11-15 and 21-27 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly failing to comply with the written description requirement. Specifically, it is asserted that “[t]he genus of a nucleotide sequence claimed is a large and variable genus including mutants and variants, which can have a wide variety of structures.” Final Office Action of October 3, 2008, at pages 3-4. It was further asserted that “[w]ith respect to the claims, the specification does not place any structure, chemical functional limitations on the polynucleotide per se. It is noted that the nucleic acid sequence that hybridizes to SEQ ID NO:37. The recitation of a nucleic acid sequence does not convey a common structure or function.” *Id.* at page 4. In addition, it was asserted that “[n]o common structural attributes identify the members of the genus,” and that “[w]hile the description of the ability of the claimed nucleic acid molecule to hybridize, may describe the molecules function, it does not describe the nucleotide sequence itself.” *Id.* Applicant notes that rejections of claims 11-15 are moot as those claims have been cancelled herein. Applicant respectfully traverses the remaining rejections as hereinafter set forth.

Applicant respectfully notes that a sequence can meet the written description requirement under *Enzo Biochem, Inc. v. Gen-Probe Inc.* through the showing “relevant identifying characteristics *i.e.* complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.

296 F.3d 1316, 1324 (Fed. Cir. 2002)

(emphasis added). Applicant respectfully notes that added emphasis on “or” which applicant submit clearly indicates that one does not have to meet each and every one of the test outlined by the *Enzo* court, but that any one of them can be met to satisfy the written description requirement.

Amended claim 21, from which all other rejected claims depend, recites “wherein the nucleotide sequence comprises a contiguous sequence which hybridizes to the full length of nucleotides 89-263 of the nucleotide sequence of SEQ ID NO:37.” Basis for the amendment to claim 21 can be found throughout the Specification, and more specifically, as follows. Paragraph 100 of the Specification as published notes that the sequence of fpbs is provided in GenBank at accession number AF438158. An alignment (using BLAST) between AF438158 and SEQ ID NO:37 appears as:

gb|AF438158.1| Streptococcus suis fibronectin/fibrinogen binding protein (fbps)
gene, complete cds; and alpha-acetolactate decarboxylase
gene, partial cds
Length=2179

Score = 320 bits (173), Expect = 2e-91
Identities = 174/175 (99%), Gaps = 0/175 (0%)
Strand=Plus/Plus

| | | | |
|-------|------|--|------|
| Query | 89 | CTCCTGACCACCTATNTGCATCAAGTGCCAAATGACCAGTCGAGTGTGCGGTTAGACAAC | 148 |
| | | | |
| Sbjct | 1198 | CTCCTGACCACCTATGTGCATCAAGTGCCAAATGACCAGTCGAGTGTGCGGTTAGACAAC | |
| 1257 | | | |
| Query | 149 | TACTATACGGGCAAGGAACCTGGAGATTGAGTTGGATGTGGCTTGACTCCTAGCCAAAAT | 208 |
| | | | |
| Sbjct | 1258 | TACTATACGGGCAAGGAACCTGGAGATTGAGTTGGATGTGGCTTGACTCCTAGCCAAAAT | |
| 1317 | | | |
| Query | 209 | GCCCAGCGGTACTTCAAGAAGTACCAAGAAACTCAAGGAGGCGGTCAAGCACCTGA | 263 |
| | | | |
| Sbjct | 1318 | GCCCAGCGGTACTTCAAGAAGTACCAAGAAACTCAAGGAGGCGGTCAAGCACCTGA | 1372 |

Applicant notes that the single gap in the alignment is where SEQ ID NO:37 recites “N” at position 104. SEQ ID NO:37, at page 38 of the Specification as published, recites that the N is a, c, g, or t. Thus, if N = T, as provided for in the description of SEQ ID NO:37, then SEQ ID NO:37 hybridizes across the full length of bases 89-163. Further description of SEQ ID NO:37 hybridizing to the genomic DNA comprising the complement of the nucleotide sequence encoding for a fibronectin-/fibrinogen-binding protein of *Streptococcus suis* is provided at paragraphs 82 and 104-109 of the Specification as filed where SEQ ID NO:37 is used to clone

the gene encoding for a fibronectin-/fibrinogen-binding protein of *Streptococcus suis* and the gene demonstrated to have the recited function. Applicant further notes that the gene encoding for a fibronectin-/fibrinogen-binding protein of *Streptococcus suis* isolated using SEQ ID NO:37 placed into an expression construct (paragraphs 86 and 86 of the Specification as published) which, by definition is a double stranded nucleic acid molecule. Because the molecule is double stranded, it inherently includes the full length of bases 89-163 of SEQ ID NO:37 on the complementary strand to the strand comprising the sequence provided in AF438158. Thus, Applicant respectfully submits that an isolated or recombinant nucleic acid molecule comprising a contiguous sequence which hybridizes to the full length of nucleotides 89-263 of the nucleotide sequence of SEQ ID NO:37 is fully described by the specification.

Applicant notes that because the nucleotide sequence is required to hybridize to hybridizes to the full length of nucleotides 89-263 of the nucleotide sequence of SEQ ID NO:37, a common structure for all the claimed sequence is specifically required by this element of the claim. More specifically, in order to hybridize to the full length of nucleotides 89-263, the sequence must comprise:

GAGGACTGGTGGATANACGTAGTTCACGGTTACTGGTCAGCTCACACGCCAATCTG
TTGATGATATGCCCGTCTTGACCTCTAACTCAACCTACACCGAAACTGAGGATCG
GTTTACGGGTCGCCATGAAGTTCTCATGGTCTTGAGTTCCGCCAGTCGTGG
ACT, wherein N is the complement of the particular base provided by SEQ ID NO:37 as noted above.

Thus, contrary to the Examiner's assertion, claim 21, as amended, provides a specific structural attribute which identifies the claimed material. Claim 21 further complies with the standard set forth in *Enzo* as claim 21, as amended, shows the relevant identifying characteristics of a partial structure and functional characteristic of hybridizing to a specific sequence under certain defined conditions where there is a known correlation between the complementary structures of the of nucleic acids and the function of hybridization.

In view of at least the foregoing, applicant respectfully submits that claim 21, as amended, complies with the written description requirement. Consequently, applicant respectfully requests the withdrawal of the rejection of claim 21 under 35 U.S.C. § 112, first paragraph, for lack of written description, and reconsideration of same.

In addition, applicant respectfully submits that claims 22-27 comply with the written description, *inter alia*, as depending, directly or indirectly, from adequately described claim 21. As such, applicant respectfully requests the withdrawal of the rejections of claim 22-27 under 35 U.S.C. § 112, first paragraph, for lack of written description, and reconsideration of same.

Rejections under 35 U.S.C. § 112, First Paragraph, Enablement

Claims 11-15 and 21-27 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly failing to comply with the enablement requirement. Specifically, the Examiner forwarded four reasons, to wit:

[T]he specification does not establish: (A) regions of a nucleotide sequence; (B) the general tolerance of the nucleotide sequence to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful. Final Office Action of October 3, 2007, at page 9.

Applicant notes that the rejections of claims 11-15 are moot as those claims are cancelled herein. Applicants respectfully traverse the remaining rejections as hereinafter set forth.

Applicant respectfully submits that claim 21, as amended, establishes at least point (A) of the Examiner noted above. Specifically, claim 21, as amended, points out a region of a nucleotide sequence: “comprises a contiguous sequence which hybridizes to the full length of nucleotides 89-263 of the nucleotide sequence of SEQ ID NO:37.” With respect to points (B)-(D) applicant notes that, in order to hybridizes to the full length of nucleotides 89-263 of the nucleotide sequence of SEQ ID NO:37, no modification of the sequence GAGGACTGGTGGATANACGTAGTTCACGGTTACTGGTCAGCTCACACGCCAATCTG TTGATGATATGCCCGTTCTTGACCTCTAACTCAACCTACACCGAAACTGAGGATCG GTTTACGGGTCGCCATGAAGTTCTTCACTGGTCTTGAGTTCCGCCAGTTCGTGG ACT may occur. Thus, the Examiner’s comments in (B)-(D) relating to modifications and possible choices are moot. Consequently, applicant respectfully submits that claim 21, as amended, is enabled as claim 21 establishes a specific region of a nucleotide sequence to which hybridize to the full length of, and that, as the full length must be hybridized to, no modification of the sequence hybridizing to the recited section is possible.

In view of at least the foregoing, applicant respectfully submits that claim 21, as amended, complies with the enablement requirement. Consequently, applicant respectfully requests the withdrawal of the rejection of claim 21 under 35 U.S.C. § 112, first paragraph, for lack of enablement, and reconsideration of same.

In addition, applicant respectfully submits that claims 22-27 comply with the enablement requirement, *inter alia*, as depending, directly or indirectly, from adequately enabled claim 21. As such, applicant respectfully requests the withdrawal of the rejections of claim 22-27 under 35 U.S.C. § 112, first paragraph, for lack of enablement, and reconsideration of same.

Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 11-15 stand rejected as assertedly being incomplete under 35 U.S.C. § 112, second paragraph. Applicant notes that claims 11-15 are cancelled herein, rendering the rejections moot.

Informalities

Claim 21 is objected to for reciting “7.2.” where the second period is improper as this is not the end of the claim. Applicant notes that appropriate correction has been made.

New claim 29

Applicant notes that new claim 29 is presented in means-plus-function format as permitted by 35 U.S.C. § 112, paragraph six. Prior to examination of claim 29, applicant notes the following:

Congress has allowed by statute for patent applicants to claim subject matter according to a means for performing a specified function.

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof. 35 U.S.C. § 112, sixth paragraph.

The United States Patent Office and the courts have established a test for according patent

applicants the benefit of reciting a claim limitation using the “means-plus-function” language allowed under 35 U.S.C. § 112 ¶ 6. That test, as provided in MPEP 2181(I), is,

A claim limitation will be presumed to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3-prong analysis: (A) the claim limitations must use the phrase “means for” or “step for;” (B) the “means for” or “step for” must be modified by functional language; and (C) the phrase “means for” or “step for” *must not be modified by sufficient structure, material, or acts for achieving the specified function.* Emphasis added for clarity.

Applicant is entitled to the benefit of 35 U.S.C. § 112 ¶ 6, because claim 29 clearly satisfies the 3-prong analysis set forth by the Patent Office. Regarding prong (A), claim 29 specifically recites “means for.” Regarding prong (B), the means for is modified by functional language, to wit: “hybridizing to the nucleotide sequence of SEQ ID NO:37 . . .” Regarding prong (C), the means for is not modified by structure, material, or acts for achieving the specified function as the remainder of the claim further defines what the function is (hybridizing under certain particular conditions) and does not provide structure, material, or acts for performing that function.

Further, once a claim is entitled to examination as a means-plus-function claim, it still must be analyzed “to determine whether there exists corresponding adequate support for such claim under 35 U.S.C. 112, first paragraph. MPEP 2181(IV).

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention. 35 U.S.C. § 112, first paragraph.

A means- (or step-) plus-function claim limitation is adequately described under 35 U.S.C. 112, para. 1, if: (1) The written description adequately links or associates adequately described particular structure, material, or acts to the function recited in a means- (or step-) plus-function claim limitation; or (2) it is clear based on the facts of the application that one skilled in the art would have known what structure, material, or acts perform the function recited in a means- (or step-) plus-function limitation. MPEP 2163 II(A)(3)(a).

Applicant notes that it is clear based on the facts of the application that one skilled in the

art would have known what structure, material or acts perform the recited function recited. Specifically, the Specification describes the cloning of a gene based on hybridization to SEQ ID NO:37 in at least paragraphs 104-106 of the Specification as published where it is taught that SEQ ID NO:37 is used as a probe to identify an fbps gene. Thus one skilled in the art would know that at least the double stranded sequence of fbps (as described in paragraph 102) would perform the recited function. Thus, claim 29, complies with the written description requirement for the means-plus function element.

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. *In re Buchner* 929 F.2d 660, 662, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). Further, a patent need not teach, and preferably omits, what is well known in the art. *Id.* To comply with the enablement requirement, it is not necessary to enable one of ordinary skill in the art to make a use a perfected commercially viable embodiment of absent a claim limitation to that effect. *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.2d 1333, 1338, 68 USPQ2d 1940, 1044 (Fed. Cir. 2003). Detailed procedures for making and using the invention may not be necessary if the description of the invention itself is sufficient to permit those of skill in the art to make and use the invention. MPEP § 2164. All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. *In re Fisher*, 4127 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

Applicant notes that the sequence described in paragraph 102 of the specification allows one skilled in the art to practice the claimed invention, given the level of knowledge and skill in the art. Specifically, one of skill in the art, using standard techniques and the information provided in paragraph 102, can clone the fbps gene of *Strep. suis* into a double stranded vector. Applicant performs precisely this paragraph 86 of the Specification as published. Applicant notes that the double stranded vector created in paragraph 86 meets all the elements of claim 29. Thus, using the teachings of the Specification and the level of knowledge and skill in the art, one skilled in the art is able to practice the claimed invention. Claim 29 thus complies with the enablement requirement.

CONCLUSION

In light of the above amendments and remarks, applicant respectfully request reconsideration of the application. If questions remain after consideration of the foregoing, or if the Office should determine that there are additional issues which might be resolved by a telephone conference, the Office is kindly requested to contact applicant' attorney at the address or telephone number given herein.

Respectfully submitted,



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